RESPIRONICS®
DEUTSCHLAND

Deckblatt

AA-SE-054	Datum: 11.11.1998
Verfasser: Anita Lang	

gültig für:

Wartung von BiPAP

Nr.	Änderung/Name		Datum:
A	Erstausgabe		11.11.1998

1. Einleitung

Diese Arbeitsanweisung beschreibt wie an BiPAP-Geräten die Wartung durchgeführt wird.

2. Vorgehensweise

2.1 Formalität

- SB ausfüllen
- Patientenwert aufschreiben
- Betriebsstunden aufschreiben

2.2 Äußere Sichtkontrolle

- Netzkabel auf äußere Beschädigung überprüfen
- Kabel
- Gehäuse
- Knöpfe
- Füße
- Geräusche beachten

2.3 Filter austauschen (bei jeder Wartung)

2.4 Eingangskontrolle

- Spannungswahlschalter + Sicherungen überprüfen
- Gerät ans Netz einstecken und einschalten
- Gerät auf IPAP-Mode stellen → Minimum einstellen
- Druckmessgerät und Testadapter (0,25") anschließen
- IPAP-Knopf langsam bis Maximum nach oben drehen und dabei verschiedene Werte einstellen. Eingestellter Skalenwert sollte vom gemessenen Wert am Druckmeßgerät nicht mehr als +/- 2 cmH_2O abweichen.
- IPAP-Knopf auf Minimum stellen
- Gerät auf EPAP-Mode stellen → Minimum einstellen
- Druckmessgerät und Testadapter (0,25") anschließen
- EPAP-Knopf langsam bis Maximum nach oben drehen und dabei verschiedene Werte einstellen. Eingestellter Skalenwert sollte vom

gemessenen Wert am Druckmeßgerät nicht mehr als +/- 2 cmH_2O abweichen.

- EPAP-Knopf auf Minimum stellen
- Manometer und Testadapter abschließen
- Gerät auf Spontanous-Mode stellen → IPAP=8; EPAP=4;
- Mit der Hand am Patientenausgang das Atmen simulieren in dem der Ausgang zu und aufgemacht wird.
  - EPAP und IPAP LED folgen der Atmungssimulierung
  - Während des Simulierens den EPAP-Kontrollknopf auf 12 drehen
  - wenn der EPAP-Druck höher als der eingestellte IPAP-Wert ist, stoppt das Gerät.
  - Gerät arbeitet auf IPAP-Druck und folgt nicht mehr der Simulierung
  - Simulieren der Ausatmung → IPAP auf 16 drehen
  - Wenn IPAP-Druck größer als der EPAP-Druck wird folgt das Gerät wieder den Similierungsrhythmus.

Merke: Der genaue Punkt der Abschaltung kann nicht definiert werden, da die Drücke eine Toleranz von +/- 2 cmH_2O haben.

- IPAP= 12; EPAP= 5 ⇒ Ausatmung mit der Hand simulieren
- Ausatmung Stoppen mit geblocktem Ausgang
- Gerät stoppt bei EPAP-Druck
- Ausatmung wieder simulieren → Gerät sollt innerhalb der nächsten drei Zyklen wieder anfangen zu triggern.
- Bei stoppen der Ausatmungssimulierung mit offenen Ausgang wird das Gerät vielleicht weiter triggern und stoppt vielleicht bei EPAP oder IPAP. Jedes Verhalten ist akzeptierbar.

Nur S/T oder S/T-D Geräte:

- Gerät auf S/T-Mode stellen
- IPAP = 12, EPAP = 5, BPM = 20
- Ausatmung mit Hand simulieren
- Ausatmung stoppen mit geschlossenen Ausgang
- Gerät stoppt bei EPAP
- Nach 3 sec. produziert das Gerät einen kurzen Luftausstoß (abhängig von der eingestellten Frequenz)
- Gerät bleibt auf EPAP ⇒ Luftausstoß alle 3 sec.
- Funktion bei verschiedenen Frequenzen überprüfen

Nur S/T oder S/T-D Geräte:

- **Gerät auf Timed-Mode stellen**
- **IPAP = 12, EPAP = 5, BPM = 20, %IPAP = 50**
- **Gerät zirkuliert zwischen IPAP und EPAP in Abhängigkeit der Frequenz und % IPAP**
- **Frequenz sollte im Bereich von +/- 10% oder +/- 2% sein (jenachdem welches größer ist)**
- **% IPAP = +/- 5%**
- **Funktion bei verschiedenen Parametern überprüfen**
- **Ausatmung mit der Hand simulieren**

Merke: **Blockieren und öffnen des Ausgangs sollte das Zirkulieren nicht beeinträchtigen.**

2.5 Innere Sichtprüfung

- **Schläuche auf Risse, festen Sitz überprüfen**
- **Steckverbindungen prüfen**
- **Ventil auf leichten Gang überprüfen**

2.6 Wenn bei Eingangskontrolle nichts festgestellt wurde
→ Run-in min 1h

2.7 Bei festgestellten Mängeln folgen sie diesen Punkten:
(siehe Service Prozedur)

- **Motor Control Board (MCB) Check**
- **Blower Assembly Check**
- **Transformer Check**
- **Valve Check**
- **BIPAP Control Board (BCB) Check**
- **Blower Pressure Check**

2.8 Bei Einstellungen und Endkontrolle folgende Schritte durchführen.

Merke: **Bei Einstellungen werden Potentiometer verstellt und die gemessenen Wert dokumentiert.**
Bei der Endkontrolle werden keine Potentiometer verstellt und die gemessenen Werte werden mit den Spezifikationen verglichen und dokumentiert.

Geräte Set-up: (siehe Zeichnung Service Manual S. 7-3)

- **Gerät ans Netz anschließen**
- **O_2 Anreicherungsadapter am Geräteausgang anschließen**
- **Durchflußmesser vom Respirator anschließen**
- **Schlauch am Durchflußmesser anschließen**
- **Manometerschlauch mit Adapter verbinden**
- **Am Ende des Schlauches ein Flußventil anschließen**
- **Führen Sie die Schritte im Service Manual ab 7-11 durch.**

Merke: Eine Sicherheitstechnische Kontrolle ist für alle BIPAP Geräte durchzuführen außer BIPAP-S und DUET.

3. Mitgeltende Unterlagen

Service Manual

4. Verteiler

1 x Service
1 x QA (Original)

erstellt am/von:	geprüft Abteilungsleiter:
T. WERNER	Lang Anita 12.11.98

1. Einleitung

Diese Prüfanweisung beschreibt die Kalibrierung sowie die Endkontrolle von BiPAP S/T 30 und S/T-D 30 Geräten.

2. Vorgehensweise

Achtung: Bevor die nachfolgenden Tests durchgeführt werden, sollte das Gerät ca. 1 Stunde warmlaufen.

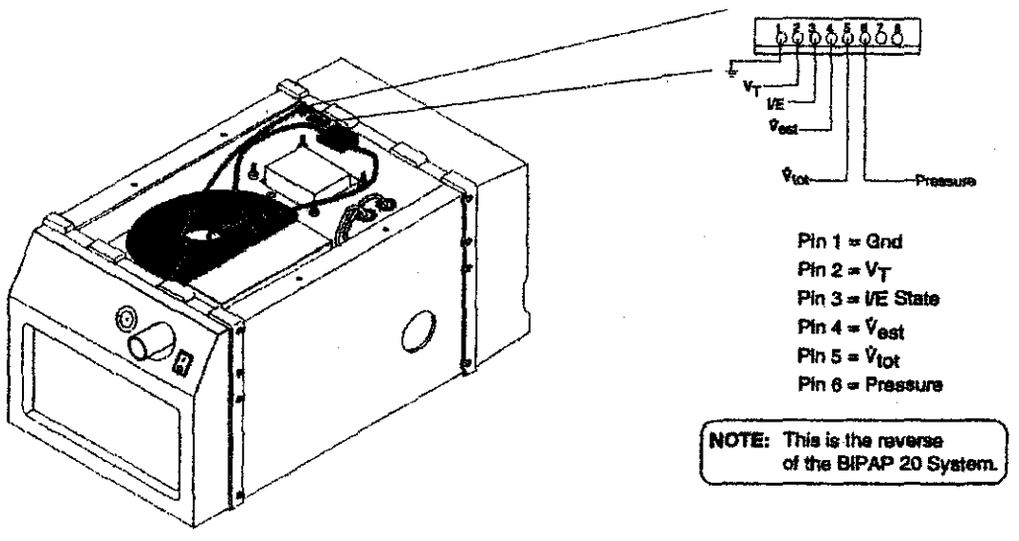


Abbildung 1

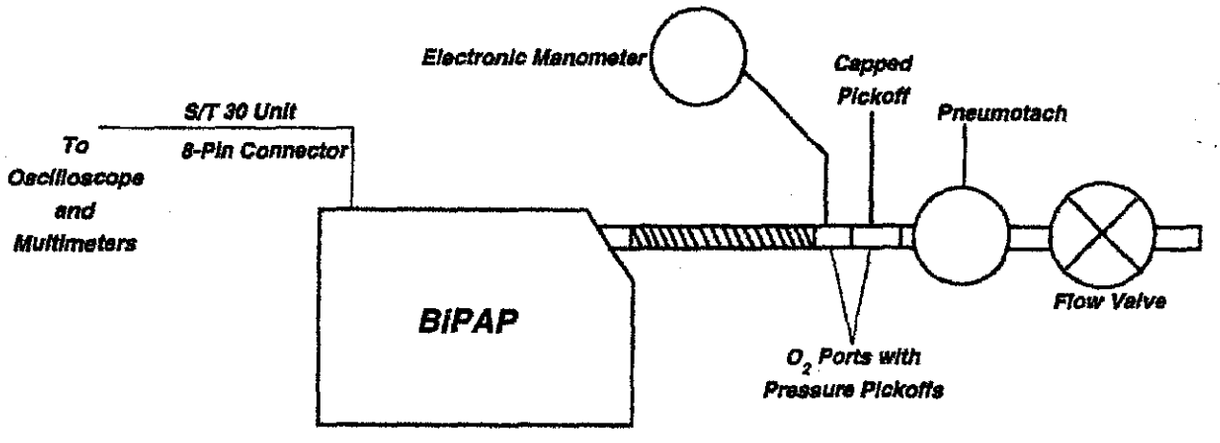


Abbildung 2

ALK

RESPIRONICS DEUTSCHLAND

Deckblatt

PA-QA-060	Datum: 25.03.1999
Verfasser: A. Lang	

gültig für:

Kalibrierung von BiPAP S/T 30 und S/T-D 30

Nr.	Änderung/Name		Datum:
A	Erstausgabe		25.03.1999

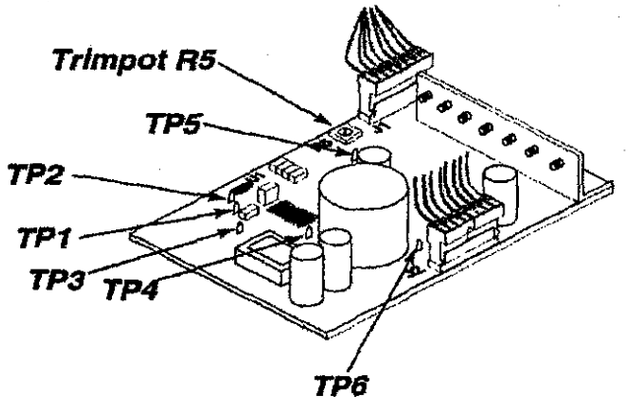


Abbildung 3

2.1 Systemeinstellung

2.1.1 Einstellung der Motorgeschwindigkeit

A) Aufbau und Einstellungen des BiPAP 30

- Der Testaufbau mit den entsprechenden Meß- und Hilfsmitteln ist in Abb. 1 dargestellt.
- Die Lage der Testpunkte und Potis ist in Abb. 3 dargestellt.
- BiPAP 30 so auf die Seite legen, daß die Bodenplatte auf dem Tisch abgelegt werden kann.
- Den roten Anschluß des Meßgerätes an TP2 des MCB und das Softwarekabel an TP4 klemmen. Meßgerät auf "Hz" stellen.
- Das BiPAP 30 auf IPAP-Modus stellen.
- IPAP-Knopf auf Maximum stellen.

B) Testprozedur

- Gerät einschalten
- Die Frequenz sollte 4800 Hz ± 20 Hz betragen. Falls nicht, R5 entsprechend einstellen.
- EPAP-Knopf drehen. Die Motorgeschwindigkeit sollte sich nicht ändern.
- Modusknopf auf EPAP stellen. EPAP auf Maximum einstellen.
- Die Frequenz sollte 4800 Hz ± 20 Hz betragen.
- IPAP-Knopf verstellen. Die Motorgeschwindigkeit sollte sich nicht ändern.
- Gerät ausschalten und Frequenzmeßgerät abschließen.

2.1.2 Durchflußwandler einstellen

A) Aufbau und Einstellungen des BiPAP 30

- Der Testaufbau mit den entsprechenden Meß- und Hilfsmitteln ist in Abb. 1 dargestellt.
- Ein Schlauchsystem mit 1,8m Länge am Patientenausgang des BiPAP anschließen.
- Externes Flußventil schließen.
- Modusknopf auf IPAP stellen.
- IPAP auf Maximum einstellen.

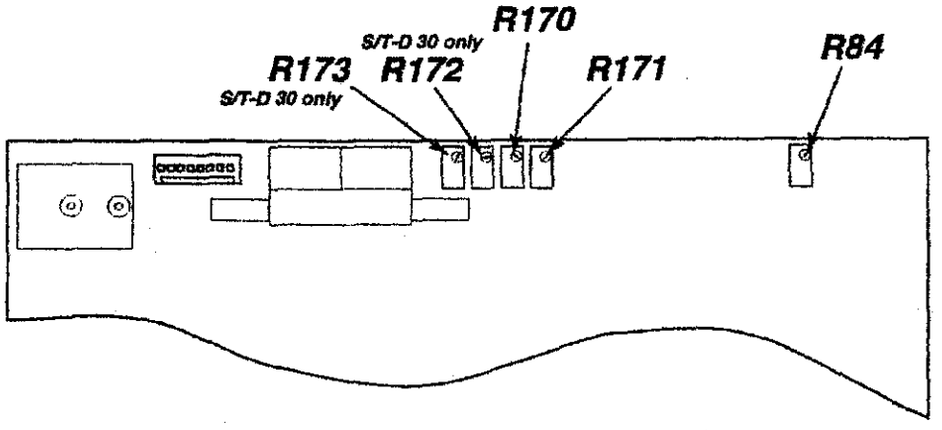


Abbildung 4

B) Testprozedur

- V_{tot} = 0,000V ± 0,010V; Einstellung an R171.
- Externes Flußventil auf 60 l/min ± 1 l/min einstellen.
- V_{tot} = 1,000V ± 0,010V; Einstellung an R170.
- Externes Flußventil schließen. Null Fluß sollte V_{tot} = 0,000V ± 0,010V zur Folge haben.
- Sollte die Spannung bei null Fluß außerhalb der Spezifikation liegen, so müssen die vorherigen Schritte wiederholt werden.
- Flußventil auf 30, 60, 90 und 120 l/min einstellen und jeweils V_{tot} ablesen.

2.1.3 Ventil-Kontrolleinstellungen

A) Aufbau und Einstellungen des BiPAP 30

- Der Testaufbau mit den entsprechenden Meß- und Hilfsmitteln ist in Abb. 1 dargestellt.
- Flußventil schließen.
- Modusknopf auf IPAP stellen.
- IPAP-Knopf auf Maximum einstellen.

B) Testprozedur

- IPAP laut Skala auf 28 mbar drehen.
- R84 so einstellen, daß am Manometer 28 ± 0,2 angezeigt wird.
- IPAP auf 30, 24, 20, 18, 12, 6 und Minimum an der Skala einstellen und die Werte am Manometer ablesen.
- Modusknopf auf EPAP stellen und den letzten Schritt wiederholen.

2.1.4 Einstellung des Fluß zu Druck Vergleichs

A) Aufbau und Einstellungen des BiPAP 30

- Der Testaufbau mit den entsprechenden Meß- und Hilfsmitteln ist in Abb. 1 dargestellt.
- Flußventil schließen.
- Modusknopf auf IPAP stellen.
- IPAP-Knopf auf Maximum einstellen.

B) Testprozedur

- IPAP auf 29,0 ± 0,1 mbar am Manometer bei 0 l/min einstellen.
- Flußventil auf 50 und 100 l/min ± 1 einstellen. Die Druck- und Flußwerte für jede Einstellung dokumentieren.
- IPAP auf 24,0 ± 0,1 mbar am Manometer bei 0 l/min einstellen.
- Flußventil auf 50 und 100 l/min ± 1 einstellen. Die Druck- und Flußwerte für jede Einstellung dokumentieren.
- IPAP auf 18,0 ± 0,1 mbar am Manometer bei 0 l/min einstellen.
- Flußventil auf 50 und 100 l/min ± 1 einstellen. Die Druck- und Flußwerte für jede Einstellung dokumentieren.
- IPAP auf 12,0 ± 0,1 mbar am Manometer bei 0 l/min einstellen.
- Flußventil auf 50 und 100 l/min ± 1 einstellen. Die Druck- und Flußwerte für jede Einstellung dokumentieren.
- IPAP auf 6,0 ± 0,1 mbar am Manometer bei 0 l/min einstellen.
- Flußventil auf 50 und 100 l/min ± 1 einstellen. Die Druck- und Flußwerte für jede Einstellung dokumentieren.

2.1.5 Druckmonitor Einstellung (nur S/T-D)

A) Aufbau und Einstellungen des BiPAP 30

- Der Testaufbau mit den entsprechenden Meß- und Hilfsmitteln ist in Abb. 1 dargestellt.
- Flußventil schließen.
- Modusknopf auf IPAP stellen.
- IPAP-Knopf auf Maximum einstellen.
- Multimeter an TP1 und TP6 anschließen.

B) Testprozedur

- Mit R173 0VDC + 0,14V am Meßgerät einstellen.
- Druckschlauch zwischen O_2-Port und Drucknippel am BiPAP anschließen.
- IPAP am Manometer auf 10,0 ± 0,1 einstellen.
- Mit R172 1,0 VDC ± 0,1V am Meßgerät einstellen.
- Druckschlauch vom BiPAP abziehen und den Spannungswert ablesen. Dieser sollte 0,00-0,10VDC betragen. Druckschlauch wieder anschließen.
- IPAP auf 5, 10, 15, 20, 25 und 28 ± 0,1 einstellen und die Spannung für jede Einstellung dokumentieren.
- O_2-Port schließen.

2.1.6 Empfindlichkeit

A) Einstellungen des BiPAP 30

- Den 0,25" Testadapter am Patientenausgang anbringen.
- Modusknopf auf Spontaneous stellen.
- IPAP-Knopf auf 12 einstellen.
- EPAP-Knopf auf 4 einstellen.

B) Testprozedur

- BiPAP einschalten.
- Patientenluftauslaß öffnen und schließen. Das Gerät sollte zwischen EPAP und IPAP wechseln. LED's wechseln auch.

BiPAP 30 System Adjustment Data Sheet (Pre Run-In)

7.4.1 Blower Motor Speed

Hz	4780-4820 Hz

7.4.2 Flow Transducer Calibration

Flow Meter L/min	0	60
$\dot{V}_{tot}$		
Range (volts)	-0.015 to 0.014	0.985 to 1.014

7.4.3 Valve Calibration

Control Knob Setting	28
IPAP	
EPAP	
Pressure (cm H_2O)	27.7-28.3

7.4.5 Pressure Monitor Calibration (S/T-D 30 Only)

Manometer Pressure Settings	Measurement (volts)	Range (volts)
28.0		2.65 to 2.94

7.4.7 Trigger Level Verification

Time Meter Reading (End) ☐

Pass Fail
(Circle One)

Serial Number_____ Signature_____ Date_____ PASS ☐ FAIL ☐

BiPAP 30 System Final Data Sheet (Post Run-In)

7.4.1 Blower Motor Speed

	Hz	4780-4820 Hz

7.4.2 Flow Transducer Calibration

Flow Meter L/min	0	30	60	90	120
$\dot{V}_{tot}$					
Range (volts)	-0.035 to 0.034	0.350 to 0.640	0.850 to 1.140	1.300 to 1.690	1.750 to 2.240

7.4.3 Valve Calibration

Control Knob Setting	Min	6	12	18	24	30
IPAP						
EPAP						
Pressure (cm H_2O)	<2.5	3.5 to 8.4	9.5 to 14.4	15.5 to 20.4	21.5 to 26.4	27.5 to 32.4

7.4.4 Pressure vs. Flow Calibration

Flow Valve Settings	50	100	
Manometer Pressure Settings			Pressure (cm H_2O)
6.0			4.5 to 7.5
12.0			10.5 to 13.5
18.0			16.5 to 19.5
24.0			22.5 to 25.5
29.0			27.5 to 30.5

7.4.5 Pressure Monitor Calibration (S/T-D 30 Only)

Manometer Pressure Settings	Measurement (volts)	Range (volts)
0.0		-0.15 to 0.14
5.0		0.35 to 0.64
10.0		0.85 to 1.14
15.0		1.35 to 1.64
20.0		1.85 to 2.14
25.0		2.35 to 2.64
28.0		2.65 to 2.94

7.4.6 Blocked and Unblocked Watts

WATTS			
Blocked		Unblocked	
	<110		<110

7.4.7 Trigger Level Verification

Pass	Fail
(Circle One)	

7.6.3 & 7.6.4 Spontaneous & Spontaneous/Timed

	Spont.	Spont/Timed
S/T		Pass/Fail
S/T-D		Pass/Fail
	4.40 to 5.95 sec	Circle One

7.6.5 Timed Mode Verification

	BPM min	%IPAP min	BPM max	%IPAP max
S/T				
S/T-D				
Range	10 to 30 sec	5 to 15%	1.8 to 2.2 sec	85 to 95%

7.6.6 DCP Verification (S/T-D 30 Only)

Pass	Fail
(Circle One)	

Time Meter Reading (End) _____

Serial Number_____ Signature_____ Date_____ PASS ☐ FAIL ☐

2.2 Endtest

2.2.1 Überprüfen der Systemeinstellung

- Wiederholen aller Prüfungen in Abschnitt 2.1 ohne Einstellungen vorzunehmen.
- Alle Meß- und Hilfsmittel zur Fluß- und Druckmessung entfernen.
- Den 0,25" Testadapter anbringen.

2.2.2 Überprüfung des Modus Spontaneous

A) Aufbau und Einstellungen des BiPAP 30

- Kanal 1 des Oszilloskops an TP2 und Kanal 2 an TP4 anschließen (Abb. 1).
- Timebaseeinstellung 1s und die Kanäle auf 500mV.
- Modusknopf auf Spontaneous stellen.
- IPAP-Knopf auf 12 einstellen.
- EPAP-Knopf auf 4 einstellen.

B) Testprozedur

- Patientenluftauslaß verschließen. Die Signale am Oszilloskop sollten wie in Abbildung 6 aussehen.
- Abbildung 7 anschauen. Testadapter öffnen. V_T-Signal sollte für ungefähr 1s ansteigen. Dann den Testadapter wieder verschließen.
- Das V_T-Signal sollte sich nach 4,4-5,95 s wieder zurücksetzen. Nach der Rücksetzung des V_T-Signals das Scope anhalten.
- Die Zeit zwischen dem Verschließen und Rücksetzen messen.
- Überprüfen, daß die EPAP-Einstellung größer ist als IPAP => IPAP arbeitet
- Testadapter öffnen und schließen. Gerät sollte zwischen EPAP und IPAP wechseln.

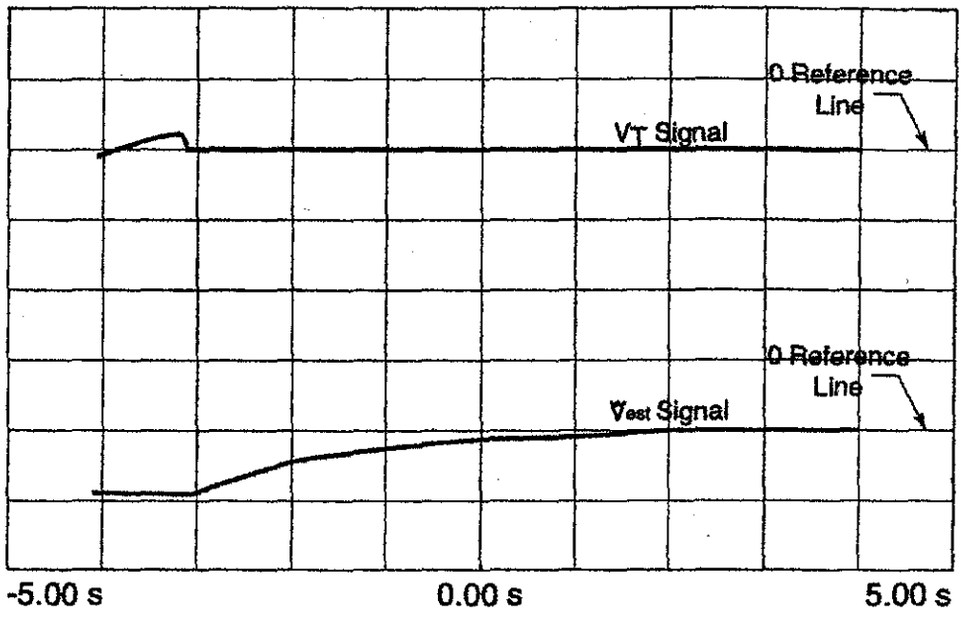


Abbildung 6

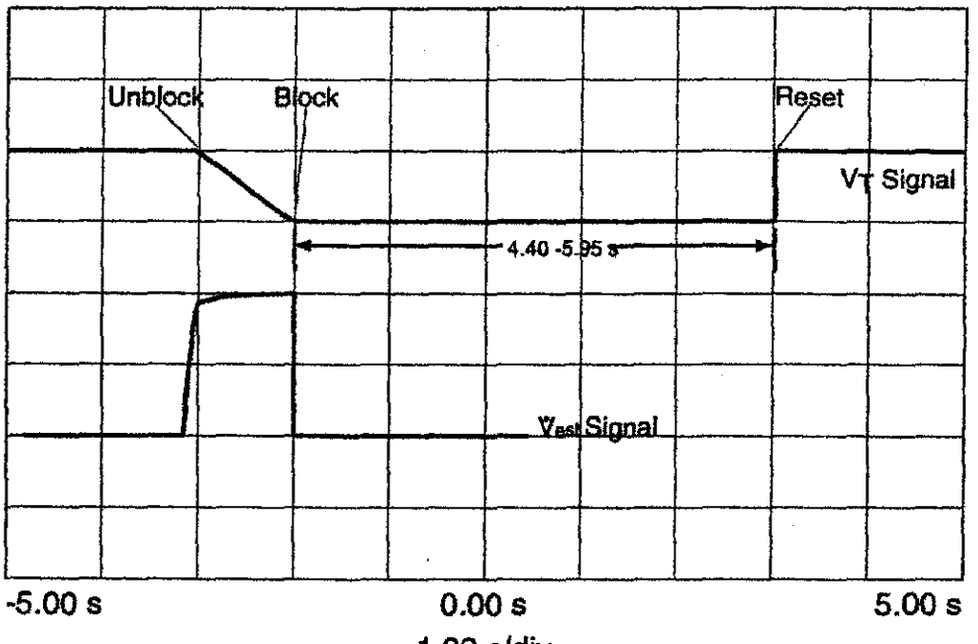


Abbildung 7

Achtung: Die Bilder zeigen die Signale für ein BiPAP S/T-~~D~~ 30. Für das BiPAP S/T~~D~~30 sind die V_T-Signale invertiert.

S/T-D 30 sind invertiert

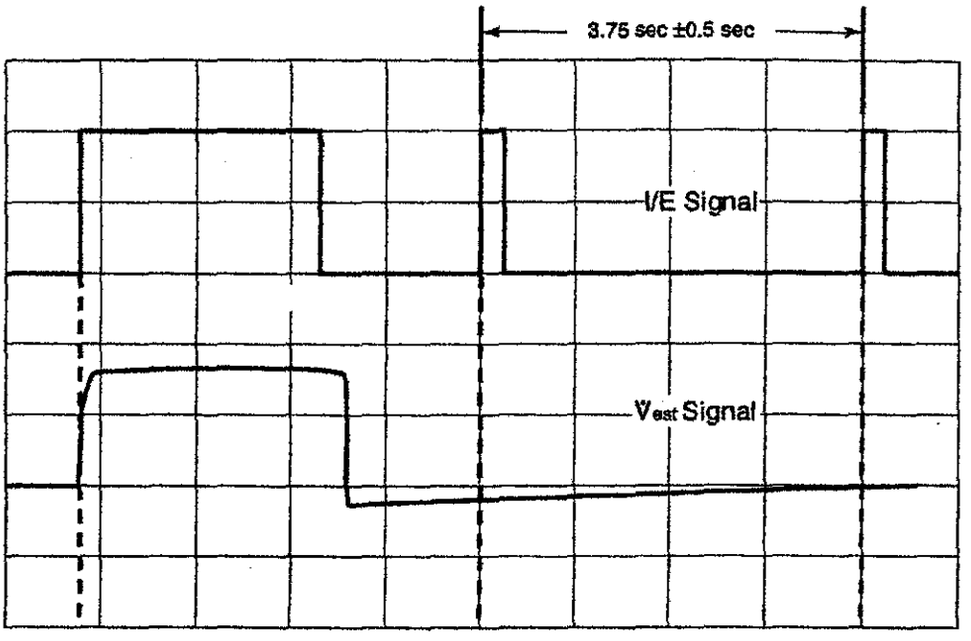
2.2.3 Überprüfung des Modus Spontan/Zeitgesteuert

A) Aufbau und Einstellungen des BiPAP 30

- Kanal 1 des Oszilloskops an TP3 und Kanal 2 an TP4 anschließen (Abb. 1).
- Timebaseeinstellung 1s, Kanal 1 auf 5V und Kanal 2 auf 500mV.
- Modusknopf auf Spontan/Zeitgesteuert stellen.
- IPAP-Knopf auf 12 einstellen.
- EPAP-Knopf auf 4 einstellen.
- BPM-Knopf auf 16 einstellen.

B) Testprozedur

- Testadapter schneller öffnen und schließen als die Frequenzeinstellung. Gerät wechselt zwischen EPAP und IPAP.
- Wenn dies schneller als die eingestellte Frequenz geschieht, sollte der zeitgesteuerte Impuls nicht erfolgen.
- Wenn das Gerät auf EPAP läuft Testadapter schließen. Die Frequenz-LED leuchtet.
- Der zeitgesteuerte Impuls erfolgt.
- Testadapter öffnen, bis das Gerät auf IPAP steht. Testadapter verschließen, bis zwei Signale auf dem Oszilloskop erscheinen (s. Abb. 8).
- Das Scope anhalten.
- Die Zeit zwischen dem ersten und zweiten Puls messen. Sie sollte 3,75 ± 0,75s betragen.



1.00 s/div

Abbildung 8

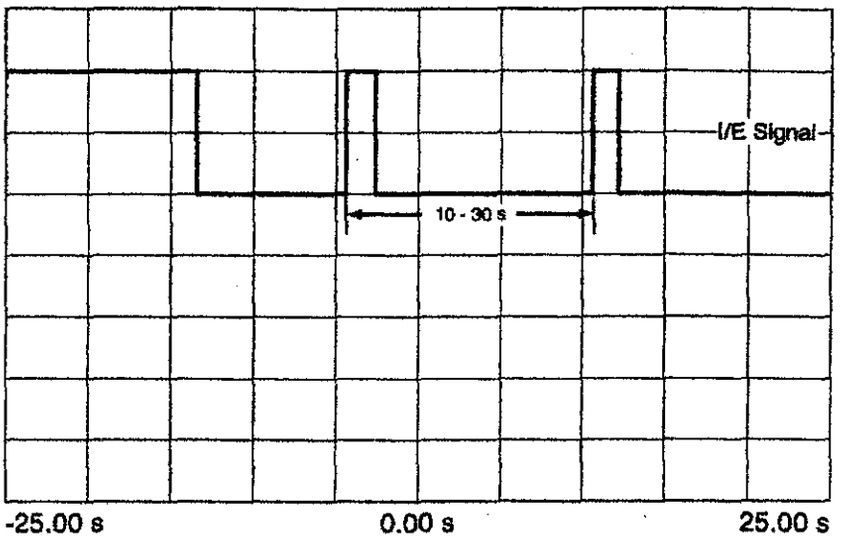
2.2.4 Überprüfung des Modus Zeitgesteuert

A) Aufbau und Einstellungen des BiPAP 30

- Kanal 1 des Oszilloskops an TP3.
- Timebaseeinstellung 5s, Kanal 1 auf 5V .
- Modusknopf auf Zeitgesteuert stellen.
- IPAP-Knopf auf 12 einstellen.
- EPAP-Knopf auf 6 einstellen.
- %IPAP-Knopf auf 10% (Minimum) einstellen.
- BPM-Knopf auf Minimum einstellen.

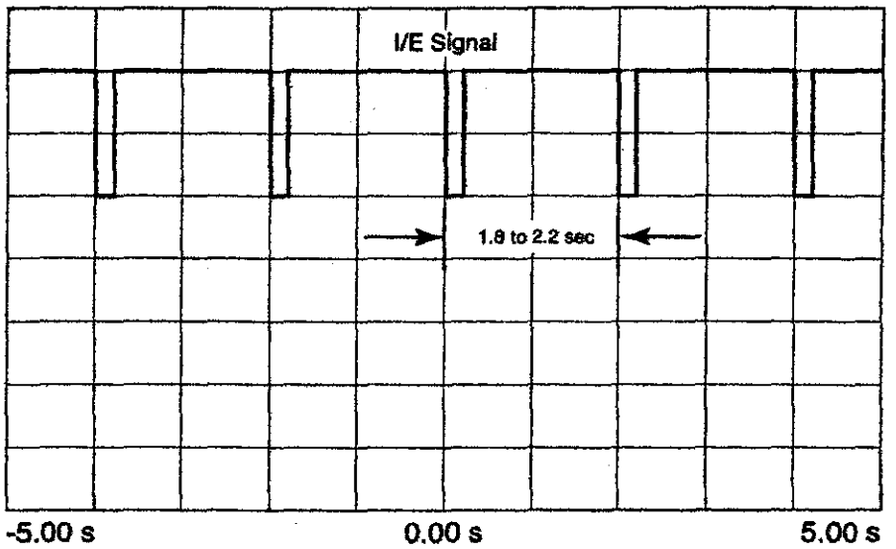
B) Testprozedur

- Periode des I/E-Signals sollte 10-30s betragen (s. Abb. 9).
- BPM-Knopf auf Maximum und %IPAP-Knopf auf 90% einstellen.
- Timebase am Oszilloskop auf 1s stellen.
- Anzeige löschen.
- Die Periode des I/E-Signals sollte 1,8-2,2s und der durchschnittliche duty cycle 90% betragen.



period	17.7146 s	Spec = 10 s to 30 s
duty cycle	10%	Spec = 5% to 15%

Abbildung 9



period	1.97605 s	Spec = 1.8 s to 2.2 s
duty cycle	89.247%	Spec = 86% to 95%

Abbildung 10

2.2.5 Überprüfung der Bedienkonsole

A) Aufbau und Einstellungen des BiPAP 30

- Testadapter 0,25" anschließen.
- Bedienkonsole anschließen.

B) Testprozedur

- Bedienfeld am Gerät sollte nicht mehr aktiv sein.
- DCP Null sollte alle Signale auf 0V setzen.
- DCP Cal sollte Durchfluß, Flow est auf ±0,5V Rechtecksignale und das Volumen auf 0,5V Sägezahn setzen.
- IPAP-Modus sollte den IPAP auf aktiv setzen und die IPAP-LED leuchtet.
- EPAP-Modus sollte den EPAP auf aktiv setzen und die EPAP-LED leuchtet.
- Spontan-Modus sollte beim Öffnen und Schließen reagieren.
- Im S/T Modus sollte es sich wie im Schritt vorher verhalten. Adapter schließen => zeitgesteuerte Pulse sind aktiv.
- Im T-Modus sollten die Frequenz und %IPAP Kontrollknöpfe arbeiten. IPAP auf 12 und EPAP auf 6 einstellen.

3. Mitgeltende Unterlagen

Keine

4. Verteiler

1 x Service
1 x QA (Original)

erstellt am/von:	geprüft Abteilungsleiter:
Lang Anita 25.03.99	Lang Anita 25.03.99

RESPIRONICS®
DEUTSCHLAND

Deckblatt

KA-SE-010	Datum: 13.11.1998
Verfasser: Anita Lang	

gültig für:

Kalibrierung des Atemweg-Druckmonitors

Nr.	Änderung/Name		Datum:
A	Erstausgabe		13.11.1998

1. Einleitung

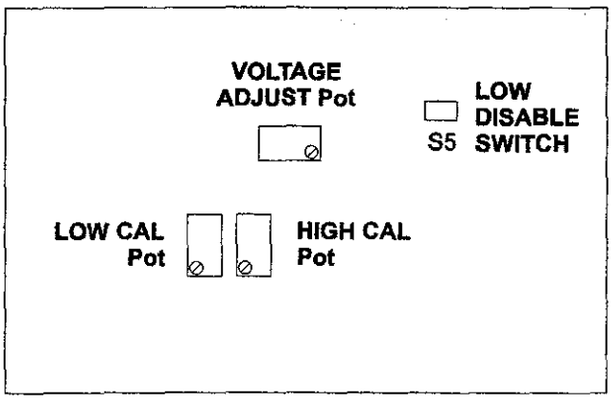
Eine vollständige Kalibrierung wird alle drei Monate empfohlen. Die ZERO ADJUST-, HIGH CAL- und LOW CAL-Poti ermöglichen vielfältigste Justiermöglichkeiten. Der Spannungsabfall innerhalb dieses Netzwerks begrenzt den Einstellbereich der LOW SET- und HIGH SET-Poti auf Werte, die den Atemweg-Drücken von 2 - 25 cm bzw. 2 - 50 cm H_2O entsprechen. Da der Strom sowohl durch das HIGH - als auch durch das ZERO ADJUST-Poti fließt, beeinflussen Veränderungen eines Poti auch den Spannungsabfall an den anderen. Verwenden Sie ein geeichtes Digitalmanometer oder ein Manometer mit Wassersäule, um die Anzeige des Druckmessers zu überprüfen.

2. Vorgehensweise

Vorsicht: Die elektronischen Komponenten dieses Geräts können durch statische Aufladung beschädigt werden. Die Kalibrierung muß an einem Anti-Statik-Arbeitsplatz durchgeführt werden.

2.1 Entfernen Sie die Abdeckung des APM, indem Sie zunächst die beiden Schrauben an der Unterseite des APM lösen und dann die Abdeckung vorsichtig abheben.

2.2 Überprüfen Sie die Batteriespannung an den Klemmen mit einem Digitalvoltmeter (9 VDC Nennwert).



2.3 Suchen Sie die Potis und suchen Sie den Schalter S5 auf der Platine.

2.4 Stellen Sie diese Werte an der Vorderseite ein:

a. Stellen Sie HIGH SET auf den Maximalwert (50 cm H_2O, im Uhrzeigersinn).
b. Stellen Sie LOW SET auf den Minimalwert (25 cm H2O, gegen den Uhrzeigersinn).
c. Stellen Sie DELAY auf den Minimalwert (0,5 s, gegen den Uhrzeigersinn).

2.5 Stellen Sie den Nullpunkt des mechanisches Druckmessers mit einem kleinen Schlitzschraubendreher ein.

2.6 Schließen Sie eine Luftspritze, die 50 cmH_2O liefern kann, an. Schalten Sie den APM ein (ON).

2.7 Stellen Sie HIGH SET auf 50. Geben Sie langsam Druck von 0 - 50 cmH_2O auf den Druckanschluß. Achten Sie auf den Punkt der Alarmauslösung. Stellen Sie das HIGH CAL Poti entsprechend ein.

VORSICHT Setzen Sie den APM keinem Druck über 50 cmH_2O aus. Drücke über 50 cmH_2O können den APM beschädigen.

2.8 Stellen Sie LOW SET auf 25. Vermindern Sie den Druck langsam auf 25 cmH_2O. Achten Sie auf den Punkt der Alarmauslösung. Stellen Sie das LOW CAL-Poti entsprechend ein.

HINWEIS: HIGH PRESSURE-Alarm wird ausgelöst, wenn der Druck im Atemweg über dem HIGH SET-Wert liegt. LOW PRESSURE-Alarm wird ausgelöst, wenn der Druck im Atemweg für mehr als 0,5 s unter dem LOW SET-Wert liegt.

2.9 Stellen Sie LOW SET auf 2. Erniedrigen Sie den Druck langsam auf 2 cmH_2O. Achten Sie auf den Punkt der Alarmauslösung. Stellen Sie das ZERO ADJUST-Poti entsprechend ein.

2.10 Wiederholen Sie die Schritte 7-9 und überprüfen Sie die Alarmauslösungspunkte im gesamten Arbeitsbereich so lange, bis HIGH SET und LOW SET korrekt eingestellt sind.

2.11 Stellen Sie LOW SET auf 20 cmH_2O. Stellen Sie Delay gegen den Uhrzeigersinn bis zum Anschlag ein. Lassen Sie den Druck pulsieren, um den DELAY Zeitgeber (60±5s) zu überprüfen.

2.12 Überprüfen Sie die Funktion von DISABLE (Unterbrechungstaste). Die Einstellung an S5 bedeutet: UP; oben = 60 (±5) s, DOWN; unten = 20 (±2) s. Stellen Sie den gewünschten Wert für die Unterbrechung ein.

2.13 Schalten Sie den APM aus (OFF). Entfernen Sie die Batterie. Verwenden Sie ein regelbares Netzgerät (10,0 VDC maximal und achten Sie auf die richtige Polung) anstelle der Batterie. Schalten Sie den APM ein. Vermindern Sie die Spannung des Netzgeräts langsam auf 6,0 VDC. Der REPLACE BATTERY-Alarm (Batteriewechsel) muß bei 6,6±0,2 VDC ansprechen. Justieren Sie das VOLT ADJ.-Poti um diesen Wert einzustellen. Schalten Sie den APM aus. Entfernen Sie die Anschlüsse und bauen Sie die Batterie wieder ein.

2.14 Geben Sie langsam Druck auf den Druckanschluß. Prüfen Sie, ob der INADVERTENT OFF-Alarm (Unbeabsichtigt Aus) bei 5(±1) cmH_2O anspricht.

3. Mitgeltende Unterlagen

keine

4. Verteiler

1 x Service
1 x QA (Original)

erstellt am/von:	geprüft Abteilungsleiter:
	Lang 16.11.98
	Markus Rostkowski 19-11-98

BiPAP® VENTILATORY SUPPORT SYSTEM

Models S/T 30 and S/T-D 30

Clinical Manual

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Chapter 1: General Description

The BiPAP 30 System
Models S/T 30 and S/T-D 30

The BiPAP 30 System is a positive pressure, electrically driven ventilation system with electronic pressure control. The unit's pressure controls are adjusted to deliver pressure support for patient ventilatory assistance.

The BiPAP 30 System is primarily intended to augment patient ventilation by supplying pressurized air through a patient circuit. It senses the patient's breathing effort by monitoring airflow in the patient circuit and adjusts its output to assist in inhalation or exhalation. This assistance is provided by the administration of two levels of positive pressure. During exhalation, pressure is variably positive or near ambient. The inspiratory level is variably positive and is always higher than the expiratory level.

The Respironics BiPAP 30 System responds to changes in patient flow rates that indicate movement to inhalation and exhalation. It performs reliably in sensing the patient's breathing efforts, even with the presence of most leaks in the patient circuit. Automatic adjustment of the trigger threshold in the presence of leaks is what makes the BiPAP 30 System ideal for mask-applied ventilation assistance.

The BiPAP 30 System senses air flow in the patient circuit by using a flow transducer in conjunction with the patient air outlet. The flow signal is composed of flow into the patient's lungs and flow due to leaks in the patient circuit. This flow data is continuously processed, and adjustments are automatically made to trigger thresholds. The adjustments provide high sensitivity to inspiratory effort and rapid adjustment for changing leaks while minimizing auto-triggering.

The BiPAP 30 System can operate in the following four modes. In each mode, the prescribed setting for each functional control must be determined by the physician/clinician based on appropriate patient testing and monitoring of the necessary physiologic parameters.

SPONTANEOUS (S) MODE

The unit cycles between the Inspiratory Positive Airway Pressure (IPAP) and Expiratory Positive Airway Pressure (EPAP) levels in response to patient triggering. The patient determines the respiratory rate.

SPONTANEOUS/TIMED (S/T) MODE

The unit cycles between the IPAP and EPAP levels in response to patient triggering. If the patient fails to initiate an inspiration, the unit will cycle to IPAP based on a preset interval determined by the Breaths Per Minute (BPM) control.

TIMED (T) MODE

The unit cycles between the IPAP and EPAP levels based solely on the timing intervals as determined by the rate (BPM) and inspiratory time (% IPAP) controls. The patient may superimpose spontaneous breathing over the IPAP and EPAP levels.

CONTINUOUS POSITIVE AIRWAY PRESSURE (CPAP)

With the Function Selector Knob set in either the IPAP or EPAP position, the pressure set on the corresponding dial will be delivered continuously.

Chapter 2: Warnings, Cautions, and Notes

WARNING:	Indicates the possibility of injury to the patient or the operator
CAUTION:	Indicates the possibility of damage to the device
NOTE:	Places emphasis on an operating characteristic

2.1 WARNINGS

General

- Federal law restricts these devices to sale by or on the order of a physician.
- This manual serves as a reference. It should be used in conjunction with the instructions and protocol set by the physician at the institution where the device is being used. The instructions in this manual are not intended to supersede established medical protocols regarding the use of assist ventilators.

Safety

- The BiPAP 30 System is an assist ventilator and is intended to augment the ventilation of a spontaneously breathing patient. IT MUST NOT BE USED AS A LIFE SUPPORT VENTILATOR. It is not intended to provide the total ventilatory requirements of the patient.
- The BiPAP 30 System should not be applied to patients who are incapable of maintaining life-sustaining ventilation in the event of malposition of the patient interface.
- The BiPAP 30 System is intended for use on pediatric or adult patients with:
    - chronic respiratory failure;
    - acute respiratory insufficiency;
    - acute respiratory failure; and,
    - obstructive sleep apnea syndrome.
- The BiPAP 30 System is intended for use with a Respironics, Inc. approved patient circuit only. A Respironics approved circuit consists of :
    - smooth inner lumen tubing;
    - an exhalation device such as the Whisper Swivel® or Respironics Disposable Exhalation Port Assembly; and,
    - a noninvasive patient interface (nasal mask, mouthpiece, or full face mask).

  Additional accessories may be added to the circuit to meet specific needs. Every time changes are made to the circuit configuration, the delivered pressures must be monitored at the patient connection with the unit cycling. If using other patient circuits, they must have a continuous leak exhalation port with flow comparable to Respironics exhalation ports.
- The continuous flow exhalation port (i.e., Whisper Swivel) is designed to exhaust patient exhalation from the patient circuit. Continuous flow is required for safe operation. DO NOT BLOCK OR OTHERWISE TRY TO SEAL THE GAS VENTS ON THE EXHALATION PORT.

WARNINGS continued

Service

- Wiring connections and adjustments should be performed by authorized service personnel ONLY.
- Repairs and adjustments MUST be performed by experienced personnel, fully acquainted with this equipment. Service done by inexperienced, unqualified personnel or installation of unauthorized parts could cause personal injury, invalidate the warranty, or result in costly damage. Contact Respironics, Inc. or your health care dealer if the unit fails to meet performance specifications.
- To avoid electrical shock, disconnect the electrical supply before changing the fuses.
- Replace fuses with those of the same type and rating only.

Cleaning

- To avoid electrical shock, unplug the BiPAP 30 unit before cleaning it.

2.2 Cautions

- The DCP 30 cable connector port is NOT a standard computer communications port. Connecting the output port to a computer could damage the computer and the BiPAP 30 unit.
- On BiPAP S/T-D 30 models, output signal pin connections are active. Care must be exercised to prevent electrical shorting between the pin connections.
- Only Respironics cables should be used. Use of any other cable types may cause damage to the BiPAP S/T-D 30 System.
- For patient pressure monitoring, from an external monitor, use only tubing with a smooth inner lumen between the patient circuit and monitor.
- When transporting or storing the BiPAP 30 System, precautions should be taken to avoid exposure to temperature extremes. If exposure to such temperatures has occurred, the unit should be allowed to come to room temperature before being turned on.
- The unit should be positioned on its base or rear panel for proper operation.
- The voltage selector switch must be set according to local line voltage, and the proper fuses used.
- When using Respironics smooth inner lumen tubing without a heated humidifier, the overall length of the tubing should not exceed twelve feet.
- Regularly inspect the DCP 30 cable.
- Remove the mask before turning the BiPAP 30 unit off.

2.4 Contraindications

The following conditions may contraindicate the use of a BiPAP 30 System:

a. Patients with or susceptible to pneumothorax or pneumomediastinum should be monitored closely when applying positive pressure. Pre-existing bullous lung disease may represent a relative contraindication.

b. Hypotension induced by positive pressure ventilation.

c. A history of allergy or hypersensitivity to the mask material where the risk from allergic reaction outweighs the benefit of ventilatory assistance.

d. Aspiration of gastric contents. Exercise caution when applying a full face (nasal/oral) mask to patients because of the increased possibility of aspirating gastric contents. This is particularly true in patients who are at risk for or who have been vomiting. In these patients, placement of a nasogastric suction tube may be advisable prior to the application of a full face mask.

e. Acute sinusitis or otitis media. Although it is not necessary in many patients, nasal positive pressure therapy may need to be temporarily suspended in some patients with acute sinusitis or otitis media.

f. Patient's inability to maintain a patent airway or to adequately clear secretions.

g. Life-threatening or potentially life-threatening epistaxis.

h. Patient's without an intact respiratory drive.

2.5 Patient Warnings

- Advise the patient to immediately report any unusual chest discomfort, shortness of breath, or severe headache.

- If using a full face mask, the patient should be advised not to eat or drink two to three hours prior to bedtime.

- If skin irritation or breakdown develops due to the mask, refer to the User Circuit Accessory Guide for appropriate action.

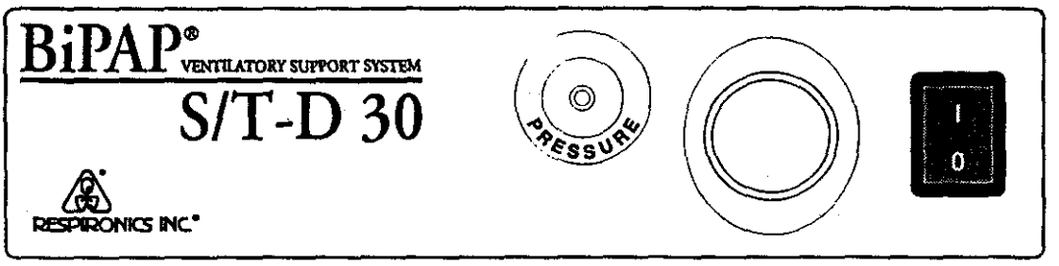
- The following are potential side effects of noninvasive positive pressure ventilation:

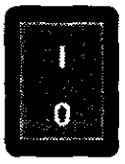
  Ear discomfort
  Conjunctivitis
  Skin abrasions due to noninvasive interfaces
  Aerophagia (Gastric Distention)

Chapter 3: Description of Controls

BiPAP 30 System Models S/T 30 and S/T-D 30

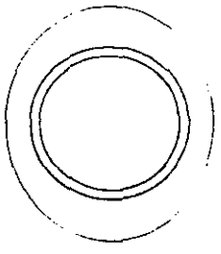
FRONT PANEL





POWER SWITCH

Turns the electrical power to the BiPAP 30 unit on and off.



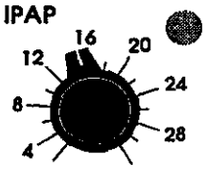
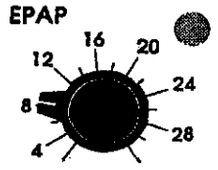
TUBING CONNECTOR

Accepts 22 mm (approximately 7/8") I.D. smooth inner lumen tubing and also accepts a mainflow bacteria filter.

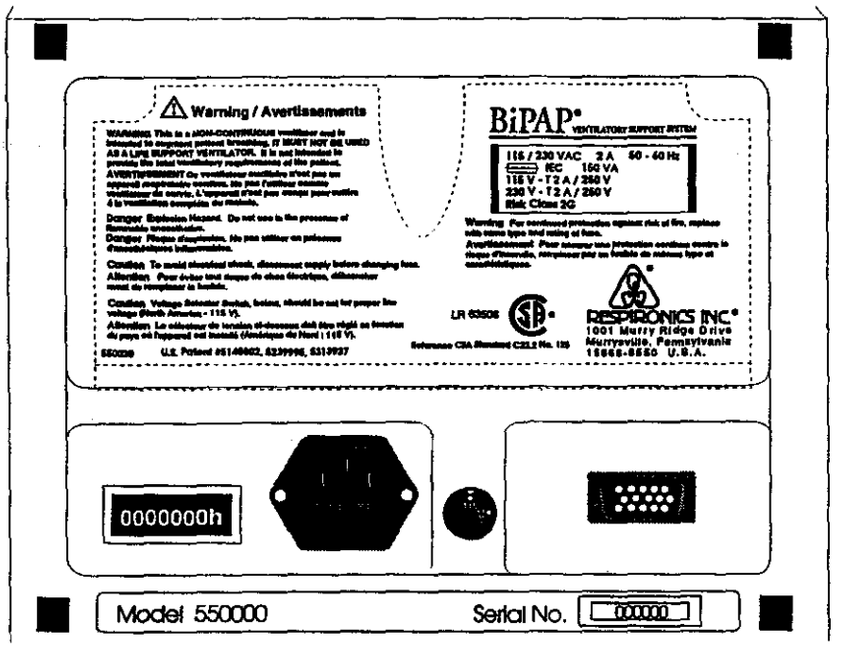
PRESSURE PORT

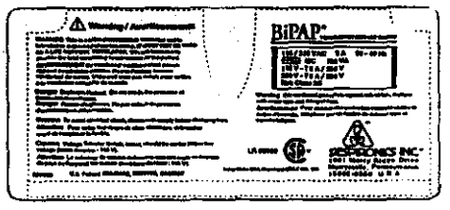
S/T-D 30 units only: Accepts manometer tubing with a smooth inner lumen. Interfaces with an internal pressure transducer to provide circuit pressure monitoring with output to a recorder. Source of the pressure display for the Detachable Control Panel 30 (DCP 30). The range is 0 to 30 cm H_2O.

CAUTION: Never connect oxygen or any positive pressure source to this port.

CONTROLS	
	**IPAP CONTROL** Inspiratory Positive Airway Pressure Active when the Function Selector Knob is in any of these four positions: IPAP, S, S/T, or T. When the BiPAP 30 unit is delivering IPAP, the adjacent LED is illuminated. Range = 4 to 30 cm H_2O.
	**EPAP CONTROL** Expiratory Positive Airway Pressure Active when the Function Selector Knob is in any of these four positions: EPAP, S, S/T or T. When the BiPAP 30 unit is delivering EPAP, the adjacent LED is illuminated. Range = 4 to 30 cm H_2O. **NOTE:** The IPAP and EPAP controls are electrically coupled. The unit will not deliver a higher EPAP than IPAP level. If the EPAP control is set higher than the IPAP control, the BiPAP 30 unit will be locked to the IPAP setting, and the IPAP LED will remain lit. This is active throughout the S, S/T, and T settings on the Function Selector Knob.

REAR PANEL





CONTROL PANEL DOOR

Contains the warnings, cautions, and electrical information necessary for safe operation of the BiPAP 30 System.

VOLTAGE SELECTOR SWITCH

Set this switch to the appropriate line voltage.

U.S.A. and Canada—115 Volts

European and other countries—Check the country's line voltage requirements for the correct setting.

ELAPSED TIME INDICATOR

Provides resolution to 1/10 hour. Runs only when the Power switch is turned ON (I).

Chapter 4: Modes of Operation

4.1 Continuous Postive Airway Pressure (CPAP)

CPAP can be delivered in either of two ways:

1. **Function Selector Knob:** IPAP
   Active Control: IPAP

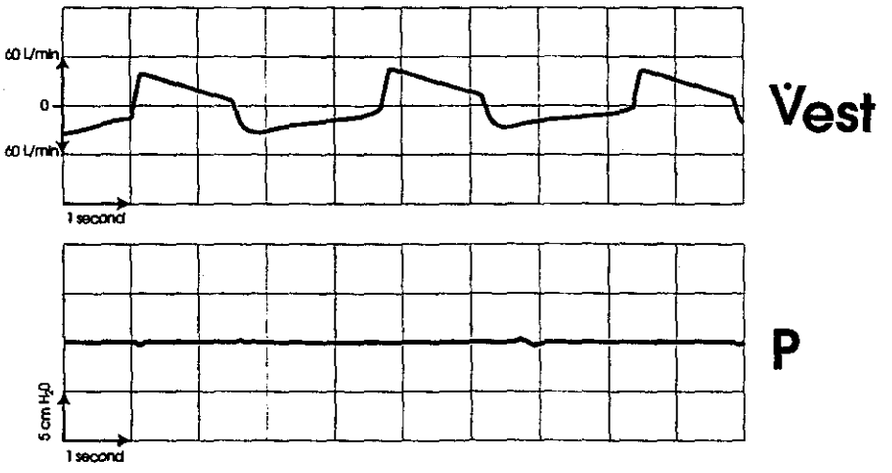
2. **Function Selector Knob:** EPAP
   Active Control: EPAP

> **NOTE:** For this combination of controls, the active pressure control being used actually indicates the level of CPAP being delivered.

In the CPAP mode, the patient breathes spontaneously at the indicated pressure level. The patient is in total control of both rate and tidal volume. The BiPAP 30 System responds as necessary to satisfy the patient's flow demand and circuit leak while maintaining the preset pressure at a stable level.

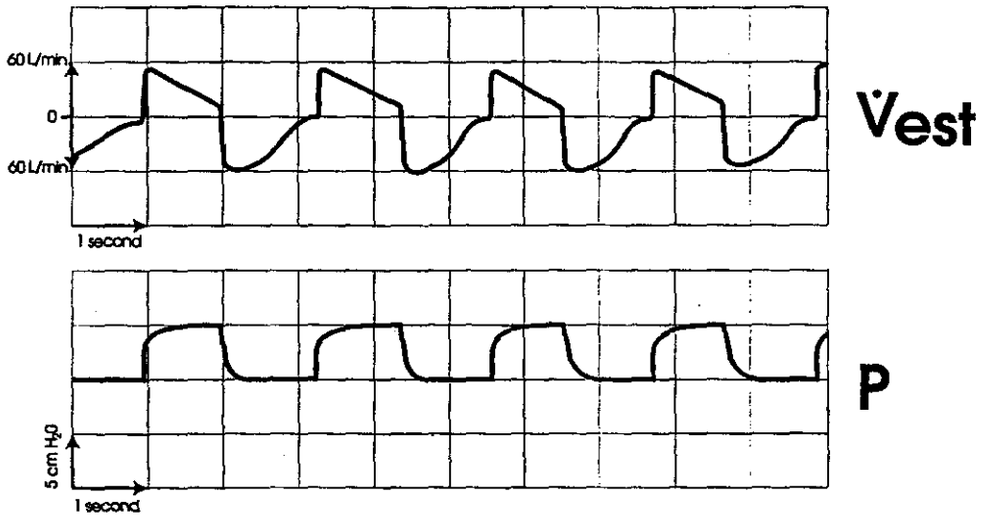
Example:

CPAP = 10 cm H_20



Example:

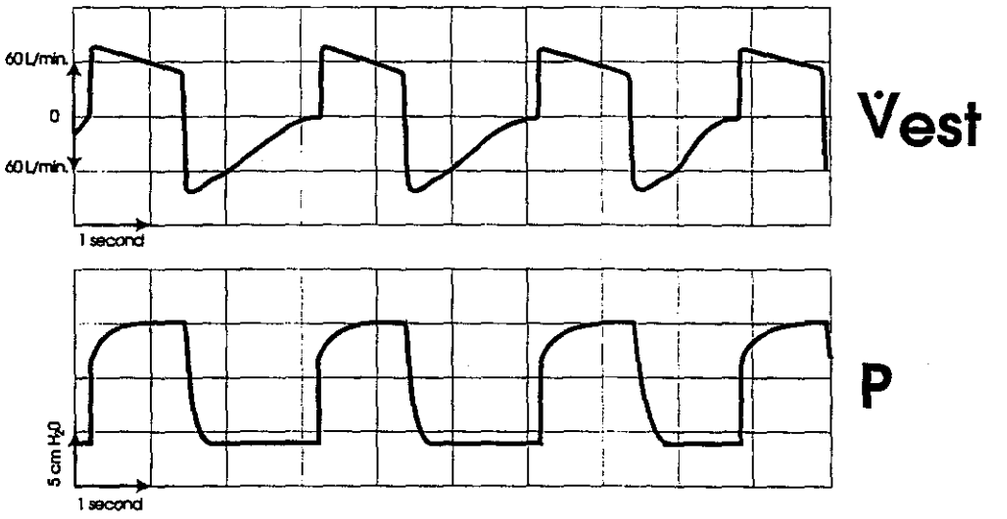
IPAP = 15 cm H_20



EPAP = 10 cm H_20

Example:

IPAP = 15 cm H_20
EPAP = 4 cm H_20

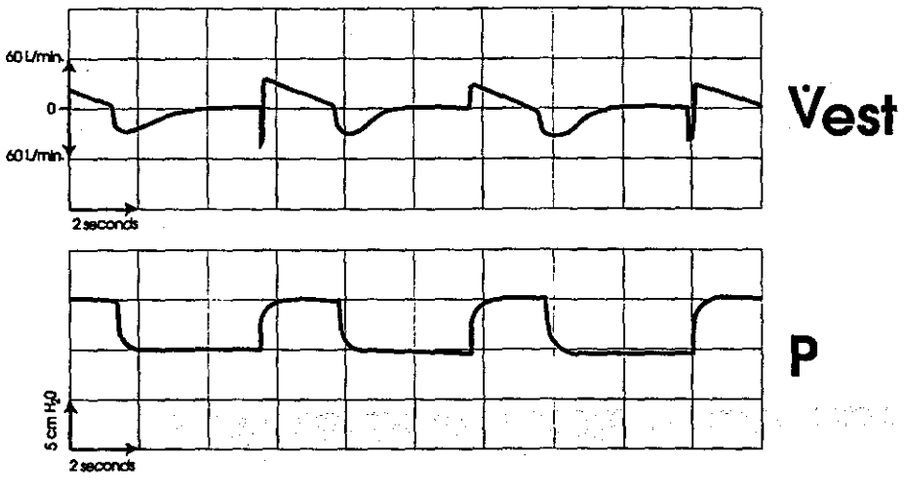


Refer to the examples and diagrams on the following page.

NOTE: **For S/T-D 30 Units only**— When using a recorder, an event marker on the $\dot{V}_{est}$ channel identifies timer-triggered breaths in the S/T mode. The event marker is a deflection below baseline at the initiation of the inspiratory flow.

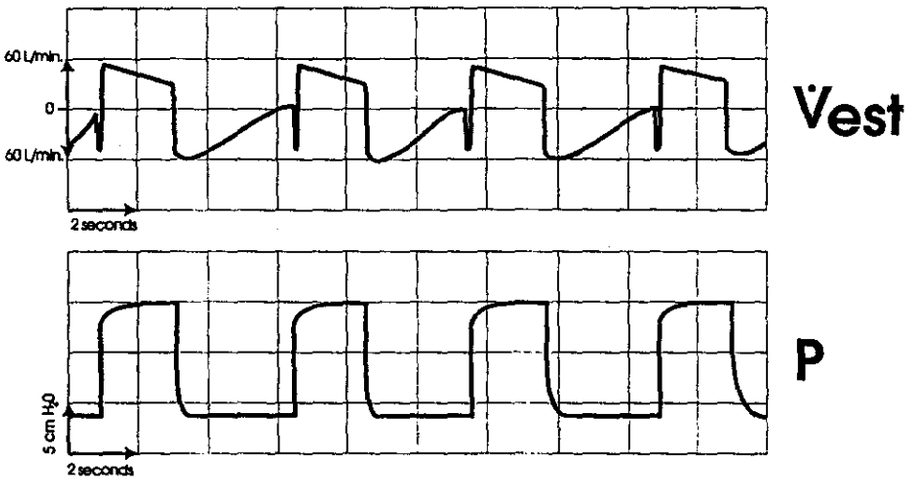
Example:

IPAP = 15 cm H_20
EPAP = 10 cm H_20
BPM = 10



Example:

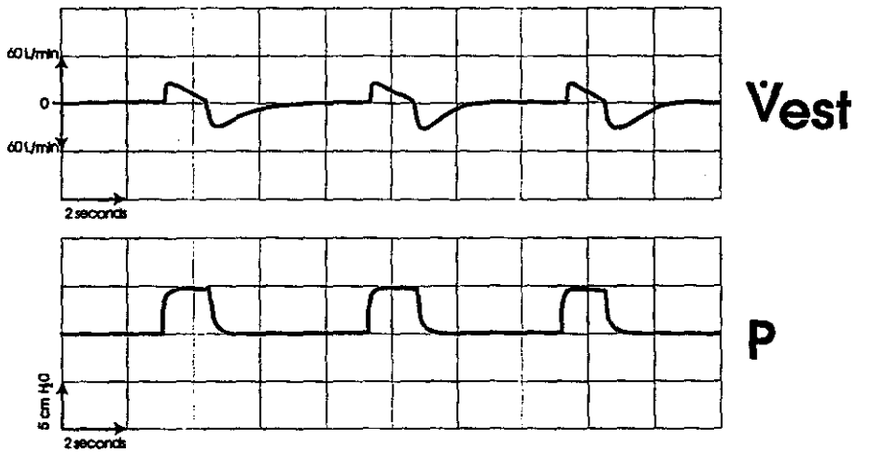
IPAP = 15 cm H_20
EPAP = 4 cm H_20
BPM = 12



Example:

IPAP = 15 cm H_20
EPAP = 10 cm H_20
BPM = 10
% IPAP = 30

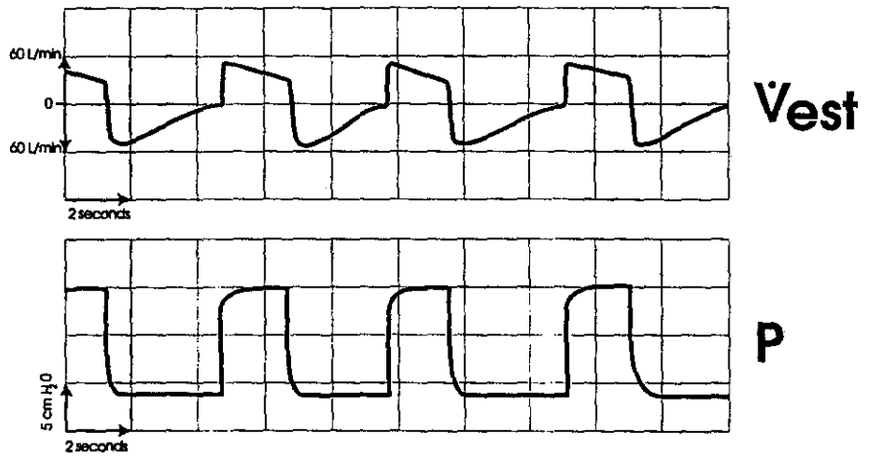
Based on these settings:
Respiratory cycle = 60 seconds/10 BPM = 6 seconds
% IPAP = 6 seconds x 30% = 1.8 seconds
EPAP = 6 seconds - 1.8 seconds = 4.2 seconds



Example:

IPAP = 15 cm H_20
EPAP = 4 cm H_20
BPM = 12
% IPAP = 40

Based on these settings:
Respiratory cycle = 60 seconds/12 BPM = 5 seconds
% IPAP = 5 seconds x 40% = 2 seconds
EPAP = 5 seconds - 2 seconds = 3 seconds



Chapter 5: Setting Up the BiPAP 30 System

Step 1 See Figure 1. Connect the inlet of a bacteria filter to the airflow outlet port on the front of the BiPAP 30 unit. Connect one end of the patient tubing to the outlet of the bacteria filter.

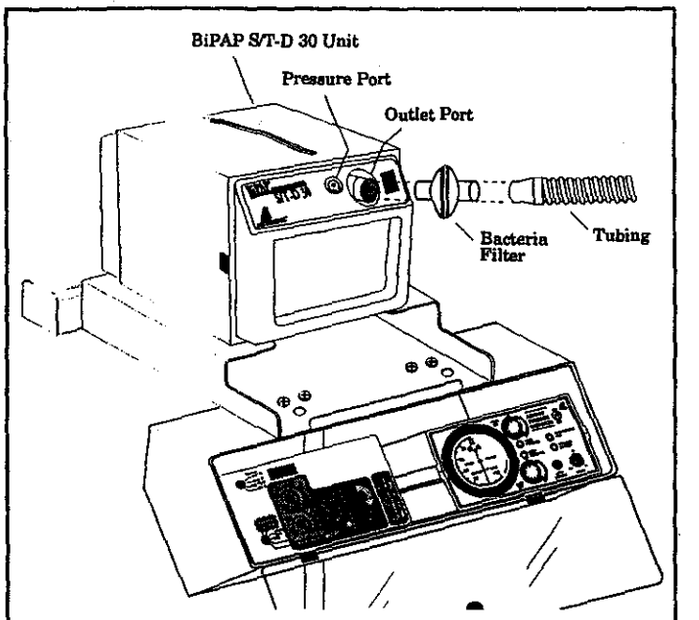


Figure 1

To protect the unit from contamination, place a low resistance main flow bacteria filter on the outlet port of the unit. The filter must be positioned in the circuit so that it is filtering air directly from the unit. If a humidifier is used, the bacteria filter should not be placed in the circuit between the outlet of the humidifier and the patient, since this can cause an increase in filter resistance.

The addition of a low resistance main flow bacteria filter does not effect the trigger sensitivity of the system. Depending upon the degree of resistance imposed by the filter, the pressure stability (the ability of the unit to maintain the delivered pressure within specified tolerances) may be affected. The filter must remain clean and dry to minimize circuit resistance. The main flow bacteria filter should be replaced in accordance with the manufacturer's specifications and instructions.

The bacteria filter should be in-line when the pressure settings are determined. If a filter is added to a system already in use, observe the patient to determine whether the pressure settings should be adjusted to compensate for any pressure drop resulting from the filter.

NOTE: Heat moisture exchangers should not be used with the BiPAP 30 System. Testing has shown that the ability of the unit to maintain the prescribed pressure is significantly affected by the addition of a heat moisture exchanger to the patient circuit.

Step 3 Plug the electrical cord into the power connector on the back of the unit. See Figure 3.

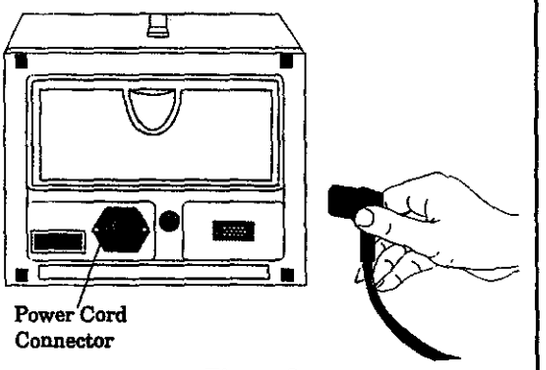


Figure 3

ep 4 Make sure the voltage selector switch on the back of the unit is set correctly. See Figure 4.

United States and Canada setting: 115 V
European and other countries: Check the country's line voltage requirements for the correct setting.

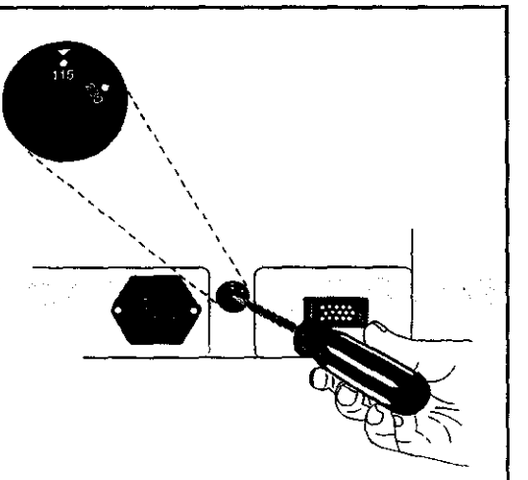


Figure 4

Step 5 Make sure the ON/OFF switch is OFF (0), then plug the electrical cord into a three-prong outlet. See Figure 5.

NOTE: In the United States and Canada, the use of a three-prong to two-prong adapter or extension cord is not recommended.

ep 6 **S/T-D 30 units only—Connecting a Recorder:**

If you are using a Detachable Control Panel 30 (DCP 30), refer to the DCP 30 instruction manual for details on connecting a recorder.

Step 7 Turn the unit on, occlude the patient port of the circuit, and **confirm the presence of flow from the exhalation port.**

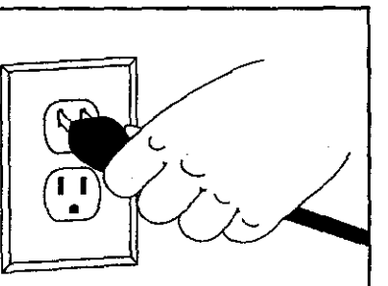


Figure 5

Chapter 6: Administering Oxygen with the BiPAP 30 System

WARNING: Oxygen should be administered only on the order of a physician.

WARNING: Oxygen supports combustion. Oxygen should not be used while smoking or in the presence of an open flame.

WARNING: Do not add oxygen to the front of the BiPAP 30 unit (at the inlet filter opening).

NOTE: When using oxygen, turn the BiPAP 30 System ON (I) before turning on the oxygen source. The oxygen should then be turned off before the unit is turned OFF (0).

To add oxygen to the circuit, a controlled, low - flow source is needed (less than 15 L/min).

- Attach the oxygen tubing to one of the sample ports on or near the patient's interface, as indicated in Figure 21a.
- Do not use a flow rate greater than 15 L/min.
- A bacterial filter must be inserted between the outlet on the unit and the circuit tubing (See Figure 6b).
- Turn the BiPAP 30 System on before turning on the oxygen supply.
- Turn off the oxygen supply before turning the BiPAP 30 System off.
- If power to the BiPAP 30 System has been turned off for any reason before the oxygen supply is turned off, allow the oxygen to dissipate from the unit before turning the BiPAP 30 System on.

When adding oxygen to the patient circuit, the liter flow is gradually adjusted until the patient's oxygenation needs are adequately met. If adequate oxygenation cannot be acheived, an alternate method of ventilatory support should be considered.

If the method of oxygen administration is changed at any time, or as patient status changes, the patient should be monitored to make sure that his or her oxygenation level is sufficient.

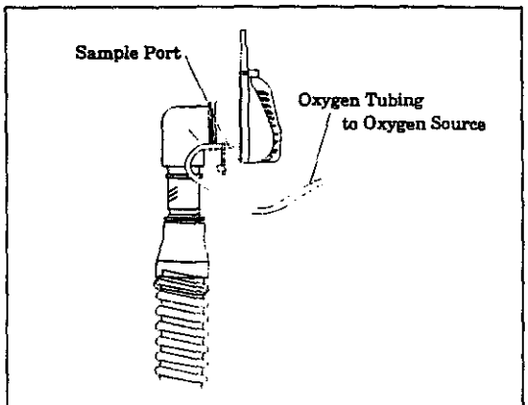


Figure 6 a

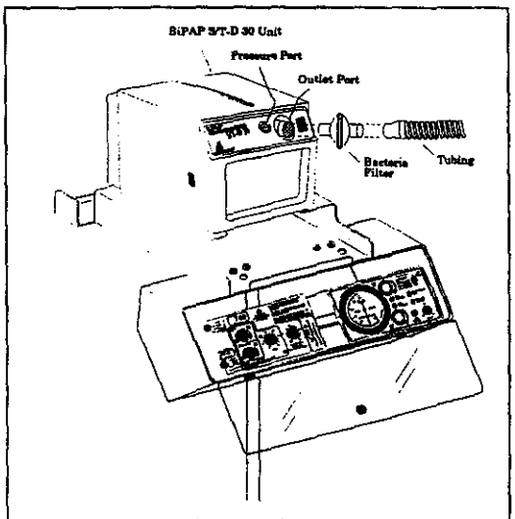


Figure 6 b

Chapter 7: Administering Aerosolized Medication with the BiPAP 30 System

Small volume nebulizers or adaptors, which allow the use of metered dose inhalers, may be added to the patient circuit. If a small volume nebulizer is used, testing has shown that the liter flow used to drive the nebulizer does not impact the functioning of the BiPAP 30 System.

The aerosol delivery system used should be added to the patient circuit on the patient side of the continuous flow exhalation port. This will minimize the impact of the continuous circuit flow on the aerosol treatment. If a main flow bacteria filter is not being used, one should be added during the treatment period to prevent any of the aerosolized medication from entering the BiPAP 30 System via the patient circuit.

Inspect the exhalation device after each aerosol administration to ensure that the ports have not been occluded by the medication. If necessary, clean or replace the exhalation device.

WARNING: Aerosolized medications may collect in the Exhalation Port. To avoid an obstruction to flow, inspection of the Exhalation Port is essential during and after medication delivery.

Chapter 8: Performance Verification

WARNING: Performance verification should be performed prior to each patient setup of the BiPAP 30 System.

NOTE: For performance verification, Respironics recommends use of a DCP 30, output to a recorder, or a manometer capable of reading pressures in centimeters of water.

Step 1 Open the control panel door on the rear of the unit. Set the Function Selector Knob to EPAP. Set EPAP to minimum.

Step 2 Connect the patient circuit following the Set-up Instructions in this manual. Connect the proximal pressure tubing to one of the pressure ports on the mask or exhalation valve.

Step 3 Adjust the settings on the control panel as follows:

Function Selector Knob: IPAP
Controls: **IPAP** 4 cm H_2O
EPAP 4 cm H_2O
BPM 10
%IPAP 30

NOTE: If you are using a BiPAP 30 Detachable Control Panel 30 (DCP 30), make all setting adjustments on the DCP 30. When the DCP 30 is connected, the remote control settings override the settings on the BiPAP 30 unit's control panel.

Step 4 For S/T-D 30 units with Pressure (P) output to a DCP 30: Connect the remaining end of the proximal pressure tubing to the BiPAP 30 pressure port on the front panel of the unit.

For S/T 30 units or S/T-D 30 units not using a DCP 30: Connect the remaining end of the proximal pressure tubing to the manometer.

Step 5 Turn the BiPAP 30 unit ON (I) and allow it to warm up for at least 15 minutes prior to performance verification.

Step 6 Completely occlude the patient circuit outlet. Turn the BiPAP 30 unit ON (I).
Verify flow from the exhalation port.
If using a recorder, verify recorder calibration:

a. Set the Function Selector Knob to Zero.
b. Calibrate the recorder to "0" for V_T, $\dot{V}_{est}$, and $\dot{V}_{tot}$.
c. Set the Function Selector Knob to Cal.
d. Calibrate the recorder to +0.5 V, -0.5 V for V_T and $\dot{V}_{est}$ and +0.5 V, 0.0 V for $\dot{V}_{tot}$.
e. Disconnect the proximal pressure tubing from the BiPAP S/T-D 30 unit, calibrate P to "0."
f. Reattach the proximal pressure tubing to the BiPAP 30 unit's pressure port.

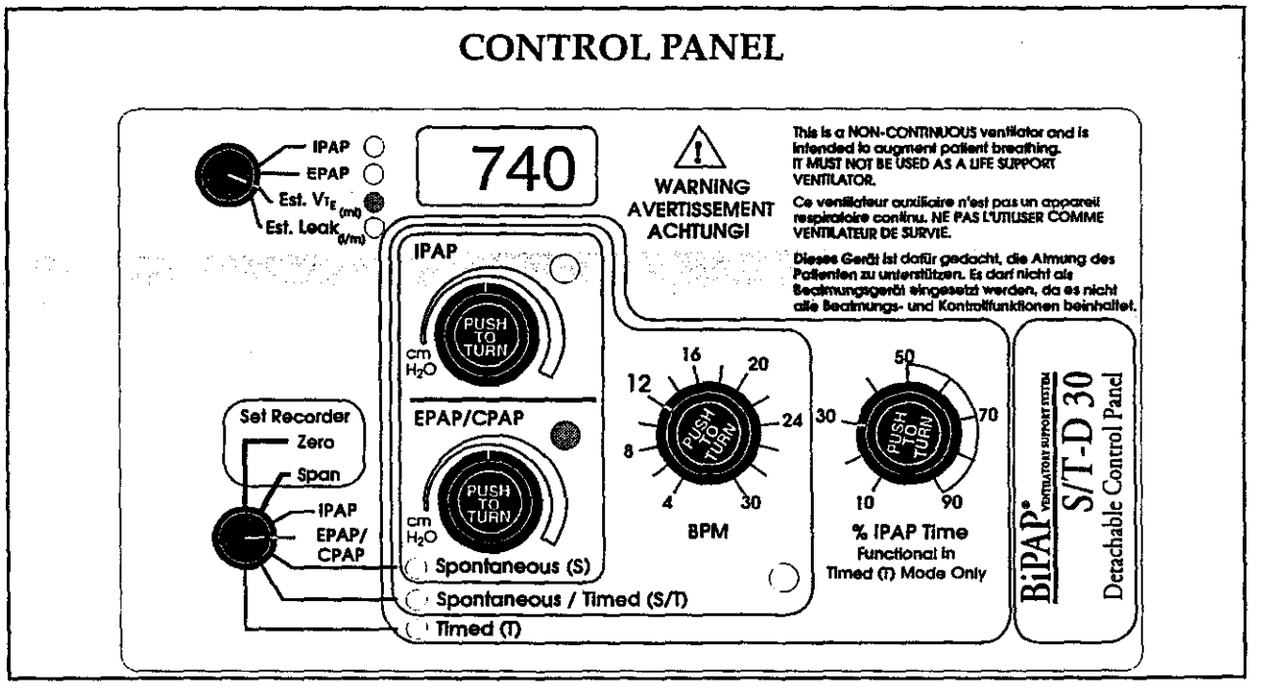
Chapter 9: Detachable Control Panel 30

9.1 General Description

The Detachable Control Panel 30 (DCP 30) is an accessory available for use with the BiPAP S/T-D 30 Ventilatory Support System. The DCP 30 combines all of the functional controls found on the rear of the BiPAP 30 unit with a selectable display that provides pressure, estimated exhaled tidal volume, and estimated circuit leak data. The DCP 30 allows the operator to make adjustments to settings from a remote location. Output connectors that allow the patient output signals to be displayed on a recorder can be found on the side of the DCP 30.

CAUTION: Use only Respironics cables designed for use with the BiPAP 30. Use of any other cable types may cause damage to the BiPAP 30 System.

9.2 Description of Controls



Refer to the Description of Controls section for complete descriptions of the panel controls. The function controls on the DCP 30 duplicate those of the BiPAP S/T-D 30 unit.

NOTE: Refer to the Detachable Control Panel 30 Operating Instructions for complete information.

9.4 Assembly Instructions

Step 1 With the power to the BiPAP S/T-D 30 System turned off, use the BiPAP S/T-D 30/Remote Cable to connect the DCP 30 to the BiPAP S/T-D 30 System. When connecting the cable to the unit, make sure the cable is securely screwed into place. (NOTE: To disconnect the cable from the unit, unscrew the pins on the sides of the cable and pull.) See Figure 7.

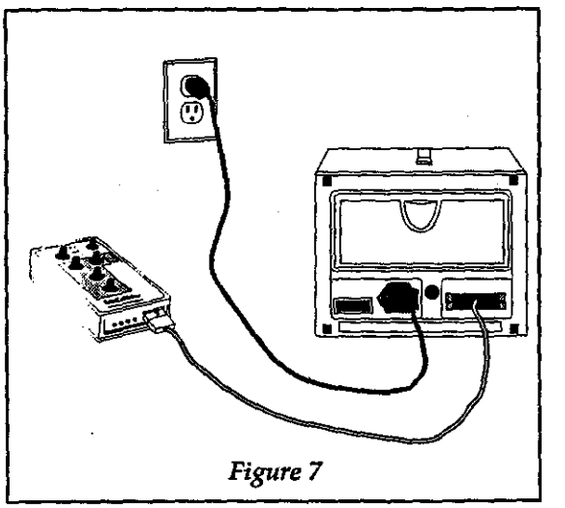


Figure 7

WARNING: Damage to the BiPAP S/T-D 30 Remote Cable may affect the operation of the BiPAP S/T-D 30 System. If the cable is damaged, replace it immediately. Never disconnect by pulling on the cable. Always use the end connectors to release the cable.

Step 2 Attach the patient circuit to the BiPAP S/T-D 30 unit and connect the proximal pressure line. See Figure 8.

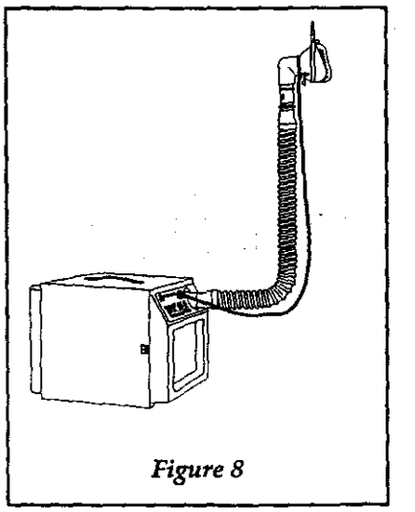


Figure 8

NOTE: For pressure monitoring, use only tubing with a smooth inner lumen.

Step 3 If patient output recordings are desired, use the Remote/ Recorder cables to connect the DCP 30 to the recorder. See Figure 9.

CAUTION: Before connecting the remote output cables, first connect the BiPAP S/T-D 30 System to a grounded outlet, then connect the DCP 30. This sequence eliminates the potential for electro-static discharge damage.

NOTE: Use only Respironics recorder cables. Do not substitute any other type of cables.

Step 4 Verify recorder calibration. Turn the BiPAP S/T-D 30 unit on.

a. Set the DCP 30 Function Selector Knob to Zero.
b. Set the recorder to "0" for V_T, $\dot{V}_{est}$, and $\dot{V}_{tot}$.
c. Set the Function Selector Knob to Span.
d. Calibrate the recorder to +0.5 V,- 0.5 V for $\dot{V}_{est}$ and $\dot{V}_{tot}$, and to 0.0 V, + 0.5 V for V_T.
e. Disconnect the proximal pressure line from the BiPAP S/T-D 30 unit and set the recorder pressure (P signal) to "0."
f. Reattach the proximal pressure line to the BiPAP S/T-D 30 System pressure port.

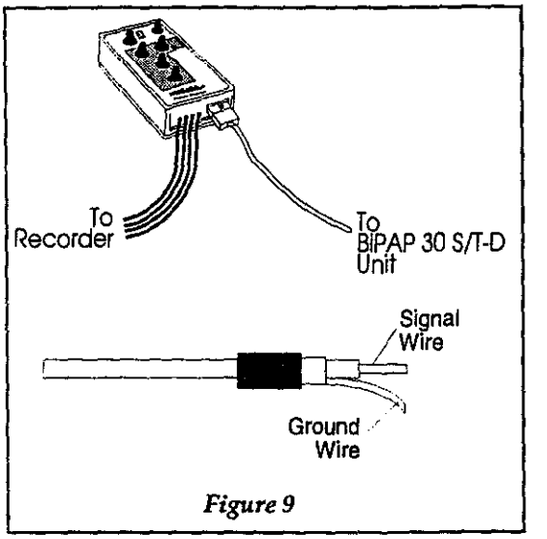


Figure 9

Chapter 10: Cleaning Instructions

10.1 Cleaning the BiPAP 30 System

CAUTION: Unplug the BiPAP 30 System before cleaning it. Do not immerse it in water or allow any liquid to enter the cabinet. Do not get the filter wet.

CAUTION: DO NOT clean any parts of the system with alcohol or cleaning solutions containing alcohol. DO NOT clean the system by steam autoclave or gas sterilization methods. These cleaning processes may harden or deform the flexible plastic parts of the system and adversely affect their function.

Step 1 Using a cloth slightly dampened with water and a mild cleanser, wipe off the outside of the BiPAP 30 System enclosure.

Step 2 Let the BiPAP 30 unit dry before plugging it in again.

10.2 Cleaning the Detachable Control Panel 30

CAUTION: Unplug the BiPAP S/T-D 30 System before cleaning it.

CAUTION: DO NOT immerse the DCP 30 in water or allow any liquid to enter the unit.

CAUTION: DO NOT clean any parts of the system with alcohol or cleaning solutions containing alcohol. DO NOT clean the system by steam autoclave or gas sterilization methods. These cleaning processes may harden or deform the flexible plastic parts of the system and adversely affect their function.

Step 1 Using a cloth slightly dampened with water and a mild cleanser, wipe off the outside of the DCP 30 enclosure.

Step 2 Let the DCP 30 unit dry before use.

10.3 Cleaning the Patient Circuit

Refer to the instructions provided with the circuit components you are using.

Chapter 11 Routine Maintenance

Refer to the Service Manual for more complete maintenance information and requirements.

11.1 Changing the Filter

CAUTION: Failure to replace a dirty filter may cause high operating temperatures of the BiPAP 30 unit, may reduce the flow, and may reduce the output pressure.

The white filter on the front of the unit is disposable and needs to be replaced after thirty days of use or sooner if it seems especially dirty.

Step 1 Turn OFF (0) the BiPAP 30 unit and unplug the electrical cord from the wall outlet and from the back of the unit.

Step 2 Locate the button in the center of the filter holder beneath the surface of the filter. Push in on the button and pull the filter out from all four sides of the filter holder. See Figure 10.

Step 3 Throw away the dirty filter. The filter is not washable.

Step 4 Center a new filter over the filter holder. Carefully push in on the center button and tuck the filter in on all four sides. See Figure 11.

Step 5 Release the button. The filter should be intact and fit securely, covering the entire holder. Remove and readjust the filter if necessary.

The filter must be in place at all times when the BiPAP 30 System is being used.

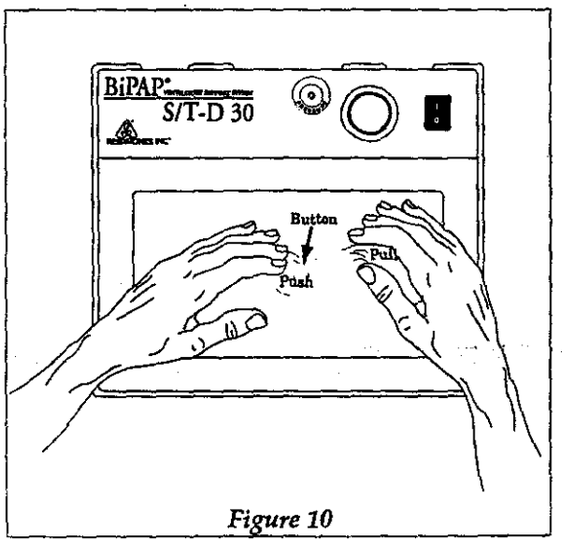


Figure 10

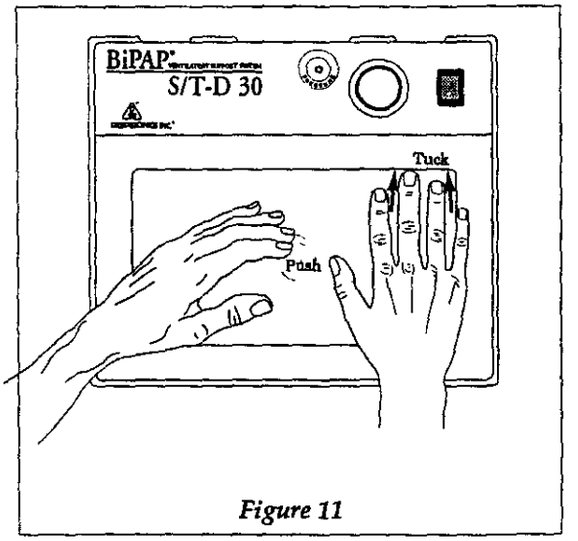


Figure 11

Chapter 12: Troubleshooting

The table below lists common problems you may have with your BiPAP 30 System and possible solutions to those problems. If none of the corrective actions listed seems to work, contact your medical equipment distributor.

PROBLEM	POSSIBLE CAUSES	CORRECTIVE ACTION
1. No air flow from the unit.	Voltage selector switch is set incorrectly.	Verify that the voltage selector switch is not set too high (i.e., your electrical line is 115 V but your switch is set on 230 V).
	Possible internal problem.	Call your medical equipment distributor. Obtain a replacement unit.
2. Unit does not operate when turned on.	Power cord not firmly connected to the unit or the wall outlet.	Check that the power cord is plugged into the unit and into the wall outlet.
	Unit not connected to a "live" outlet.	Check to ensure that the unit is plugged into a "live" outlet (e.g., plug a working lamp into the outlet).
	Unit fuse(s) has blown.	Replace the fuses. See Section 12.2. **NOTE:** Always replace both fuses at the same time. Verify that the voltage selector switch setting is correct. If the new fuses blow out, contact your medical equipment distributor.
3. Unit stops and starts.	Power cord not securely connected to the unit or the outlet.	Check that the power cord is completely connected at the rear of the unit and at the outlet.

Chapter 13: Abbreviations/Definitions

Assist Ventilator	A device designed to assist the patient's spontaneous breathing and augment ventilation.
Auto-trigger	Movement to the IPAP level in the S or S/T modes that was not caused by patient effort or the BPM control.
BPM	Breaths Per Minute. The rate at which the unit will trigger to the IPAP level in the S/T mode if the patient does not initiate a spontaneous trigger. The rate at which the unit will cycle to IPAP in the T mode.
CPAP	Continuous Positive Airway Pressure. The mode that is delivered when the Function Selector Knob is in either the IPAP or the EPAP position. A constant level of pressure that is maintained throughout the patient's respiratory cycle during spontaneous breathing.
EPAP	Expiratory Positive Airway Pressure. The pressure level that is maintained during the expiratory phase of the S, S/T, or T modes. The pressure level that is maintained continuously with the Function Selector Knob in the EPAP position.
Estimated Leak Flow Rate	The Total Flow Rate is analyzed to determine what portion of the flow through the circuit is due to intentional (Whisper Swivel or Respironics Disposable Exhalation Port) and unintentional (mask fit) leaks. This continuous unintentional leak level is referred to as the Estimated Leak Flow Rate ($\dot{V}_{leak}$).
Estimated Patient Flow Rate	The Total Flow Rate is measured, and the Estimated Leak Flow Rate is determined. The balance of the flow is due to the instantaneous changes that occur during patient inspiration/expiration. This is referred to as the Estimated Patient Flow Rate ($\dot{V}_{est}$).
Instantaneous Flow	Changes in the flow rate through the patient circuit due to inspiration/expiration.
Intentional Leak	Component of the Estimated Leak Flow Rate ($\dot{V}_{leak}$) caused by flow through a continuous bleed exhalation port such as the Whisper Swivel or the Disposable Exhalation Port.
IPAP	Inspiratory Positive Airway Pressure. The pressure level that is maintained during the inspiratory phase of the S, S/T, or T modes. The pressure level that is maintained continuously with the Function Selector Knob in the IPAP position.
%IPAP	The percent of the total respiratory cycle (the duration of which is set by the BPM control) that the unit remains at the IPAP level in the Timed mode.
P Output	**S/T-D 30 units with DCP 30 only.** Pressure. Data from an internal pressure transducer is transmitted to a recorder, providing a tracing of the delivered IPAP and EPAP levels.

$\dot{V}_{leak}$	The Total Flow Rate is analyzed to determine what portion of the flow through the circuit is due to intentional (Whisper Swivel or Respironics Disposable Exhalation Port) and unintentional (mask fit) leaks. This continuous unintentional leak level is referred to as the Estimated Leak Flow Rate ($\dot{V}_{leak}$). The $\dot{V}_{leak}$ is a calculated component of V_{tot}. Composed of intentional (Whisper Swivel or Disposable Exhalation Port) and unintentional (mask) leaks.
$\dot{V}_{tot}$ Output	**S/T-D 30 units with DCP 30 only.** Total Flow Rate. Data from the internal flow transducer is transmitted to a recorder, providing a tracing of the total flow from the unit.
V_T Output	**S/T-D 30 units with DCP 30 only.** Estimated Tidal Volume in liters. $\dot{V}_{est}$ is converted to a volume reading and transmitted to a recorder, providing a tracing of the patient's tidal volume.
V_{T_E}	Expiratory Tidal Volume.
V_{T_I}	Inspiratory Tidal Volume.

Chapter 14: Specifications

FUNCTIONS:

IPAP: Delivers set IPAP pressure continuously

EPAP: Delivers set EPAP pressure continuously

Modes: Spontaneous
Spontaneous/Timed
Timed
CPAP

PRESSURE AND FLOW CHARACTERISTICS:

Pressure Range: IPAP: 4 cm H_2O to 30 cm H_2O* at ±60 L/min flow
EPAP: 4 cm H_2O to 30 cm H_2O* at ±60 L/min flow
Pressure controls are coupled so that the unit will not deliver a higher EPAP than IPAP level when the unit is operated in the S, S/T, or T modes.

Pressure Calibration Accuracy: ± 2 cm H_2O of the indicated control setting

Pressure Setting Stability: ± 1 cm H_2O over 8 hours

NOTE: For specifications, all pressure measurements were made at the blower outlet unless stated otherwise.

*Measured at the end of a 6-foot section of smooth inner lumen tubing.

CYCLING:

Breaths per Minute (BPM): 4 to 30

Breathing Rate Accuracy: Timed mode ± 10% or 2 BPM of the indicated reading, whichever is greater

% IPAP: 10 to 90%

% IPAP Setting Accuracy: ± 10% of the indicated setting

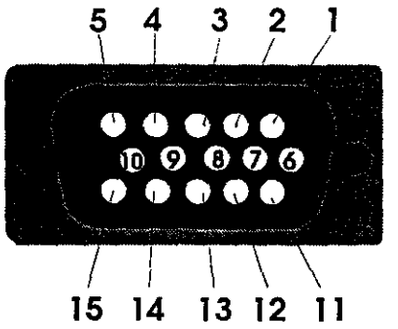
Minimum IPAP Time: Approximately 300 msec
S, S/T mode only for the spontaneous breath
Approximately 200 msec for S/T mode only for timer triggered breath

Maximum IPAP Time: 3 seconds ± 0.5 second at a constant flow rate condition of 100 L/min
S, S/T modes only

Chapter 15: BiPAP S/T-D 30 Outputs

S/T-D 30 Units Only

Output Signal Pin Connections



1. -V Unregulated
2. P (Pressure)
3. Remote Calibration
4. Remote Zero
5. Spontaneous Trigger
6. Remote Enable
7. +V Unregulated
8. Ground
9. $\dot{V}_{tot}$ (Total Flow Rate)
10. Set EPAP
11. I/E State
12. Remote IPAP
13. Remote EPAP
14. Not Used
15. Not Used

CAUTION: Care must be exercised to prevent electrical shorting between the pin connections. Only Respironics cables should be used. Use of any other cable types may cause damage to the BiPAP S/T-D 30 unit.

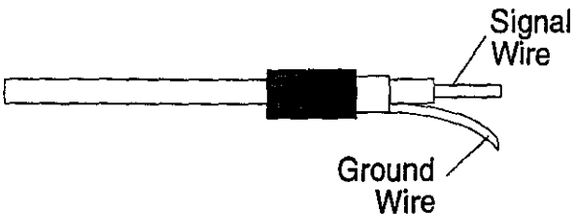
Output Signals Of DCP 30: (All Signals DC)

Estimated Patient Flow Rate - $\dot{V}_{est}$
1.0 V = 60 L/min
Range = ± 150 L/min

Total Flow Rate - $\dot{V}_{tot}$
1.0 V = 60 L/min
Range = ± 150 L/min

Estimated Tidal Volume - V_T
1.0 V = 2 liters
Range = 0 to 4 liters

Pressure - P
0.1 V = 1 cm H_2O
Range = 0 to 35 cm H_2O



CAUTION: The output signals are not isolated from the BiPAP 30 power system. The signals must be used only when connecting to a Respironics approved system with a Respironics approved cable.

Limited Warranty

Respironics, Inc. warrants that the BiPAP 30 System,shall be free from defects of workmanship and materials and will perform in accordance with the product specifications for a period of one year from the date of sale by Respironics, Inc. to the dealer. If the product fails to perform in accordance with the product specifications, Respironics, Inc. will repair or replace, at its option, the defective material or part. Respironics, Inc. will pay customary freight charges from Respironics, Inc. to the dealer location only. This warranty does not cover damage caused by accident, misuse, abuse, alteration, and other defects not related to material or workmanship.

RESPIRONICS, INC. DISCLAIMS ALL LIABILITY FOR ECONOMIC LOSS, LOSS OF PROFITS, OVERHEAD OR CONSEQUENTIAL DAMAGES WHICH MAY BE CLAIMED TO ARISE FROM ANY SALE OR USE OF THIS PRODUCT. SOME STATES DO NOT ALLOW THE EXCLUSION OR LIMITATION OF INCIDENTAL OR CONSEQUENTIAL DAMAGES, SO THE ABOVE LIMITATION OR EXCLUSION MAY NOT APPLY TO YOU.

THIS WARRANTY IS GIVEN IN LIEU OF ALL OTHER EXPRESS WARRANTIES. IN ADDITION, ANY IMPLIED WARRANTIES, INCLUDING ANY WARRANTY OF MERCHANTABILITY OR FITNESS FOR THE PARTICULAR PURPOSE, ARE LIMITED TO ONE YEAR. SOME STATES DO NOT ALLOW LIMITATIONS ON HOW LONG AN IMPLIED WARRANTY LASTS, SO THE ABOVE LIMITATION MAY NOT APPLY TO YOU. THIS WARRANTY GIVES YOU SPECIFIC LEGAL RIGHTS, AND YOU MAY ALSO HAVE OTHER RIGHTS WHICH VARY FROM STATE TO STATE.

To exercise your rights under this warranty, contact your local, authorized Respironics, Inc. dealer or Respironics, Inc. at:

1001 Murry Ridge Drive
Murrysville, Pennsylvania 15668-8550
(412/733-0200)

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